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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,573	07/17/2006	James B. Lorens	021044-004110US	4166

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EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,573	LORENS ET AL.	
	Examiner	Art Unit	
	Sumesh Kaushal Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 5-6, 16, 18, 20-24, drawn to a method of identifying a compound that modulate angiogenesis, the method comprises contacting the compound with a nucleic acid sequence that hybridizes to the nucleic acid sequence selected from SEQ ID NO:3....., and SEQ ID NO:523, classified in class 435, subclass 375.

II. Claims 1-17, 19-24 drawn to a method of identifying a compound that modulate angiogenesis, the method comprises contacting the compound with a polypeptide encoded by a nuclei acid sequence that hybridizes to the nucleic acid sequence selected from SEQ ID NO:3....., and SEQ ID NO:519 or corresponding polypeptide selected from SEQ ID NO:4 ... SEQ ID NO:524, classified in class 435, subclass 375.

III. Claims 25-32, drawn to a method of modulating angiogenesis in a subject by administering a compound that interacts with a nucleic acid sequences which hybridizes to the nucleic acid sequence selected from SEQ ID NO:3 ....SEQ ID NO:523 , classified in class 514, subclass 2.

IV. Claims 25-32, drawn to a method of modulating angiogenesis in a subject by administering a compound that interacts with a polypeptide encoded by a nucleic acid sequnce which hybridizes to the nucleic acid sequence selected from Seq ID NO:3 ....SEQ ID NO:523 , classified in class 514, subclass 2.

V. Claims 33, drawn to a method of modulating angiogenesis in a subject by administering a therapeutic effective amount of a polypeptide encoded by

a nucleic acid sequence which hybridizes to the nucleic acid sequence selected from SEQ ID NO:63 ....SEQ ID NO:498 , classified in class 514, subclass 2.

VI. Claims 34, drawn to a method of modulating angiogenesis in a subject by administering a therapeutic effective amount of a nucleic acid sequence which hybridizes to the nucleic acid sequence selected from SEQ ID NO:3 ....SEQ ID NO:523 , classified in class 514, subclass 2.

VII. Claims 35-36, drawn to an isolated nucleic acid sequences or variants thereof selected from group consisting of SEQ ID NO: 165, ... SEQ ID NO:330, classified in class 536, subclass 23.1.

VIII. Claims 37, drawn to an isolated polypeptide selected from group consisting of SEQ ID NO: 287, ... SEQ ID NO:331, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

► In order to be perfectly clear, the following Inventions within the particular Groups are NOT species elections. The nucleotide sequences and polypeptide sequences as mentioned above are structurally and functionally distinct products, which does not share a common core structure. Thus these are independent and distinct Inventions for the reasons given above and a further election of a single Invention from the elected Group is required.

With regard to Groups I, II, III, IV and VI the independent and distinct Inventions are as follows:

SEQ ID NO:3, SEQ ID NO:32, SEQ ID NO:43, SEQ ID NO:57, SEQ ID NO:63, SEQ ID NO:68, SEQ ID NO:70, SEQ ID NO:76, SEQ ID NO:81, SEQ ID NO:86, SEQ ID NO:89,

SEQ ID NO:120, SEQ ID NO:128, SEQ ID NO:139, SEQ ID NO:153, SEQ ID NO:163, SEQ ID NO:165, SEQ ID NO:169, SEQ ID NO:171, SEQ ID NO:173, SEQ ID NO:175, SEQ ID NO:183, SEQ ID NO:202, SEQ ID NO:210, SEQ ID NO:218, SEQ ID NO:227, SEQ ID NO:232, SEQ ID NO:248, SEQ ID NO:274, SEQ ID NO:285, SEQ ID NO:286, SEQ ID NO:297, SEQ ID NO:307, SEQ ID NO:308, SEQ ID NO:317, SEQ ID NO:318, SEQ ID NO:320, SEQ ID NO:323, SEQ ID NO:324, SEQ ID NO:329, SEQ ID NO:330, SEQ ID NO:340, SEQ ID NO:351, SEQ ID NO:365, SEQ ID NO:377, SEQ ID NO:384, SEQ ID NO:406, SEQ ID NO:408, SEQ ID NO:419, SEQ ID NO:421, SEQ ID NO:428, SEQ ID NO:437, SEQ ID NO:439 SEQ ID NO:445, SEQ ID NO:456, SEQ ID NO:462, SEQ ID NO:481, SEQ ID NO:484, SEQ ID NO:493, SEQ ID NO:496, SEQ ID NO:498, SEQ ID NO:519, SEQ ID NO:521, and SEQ ID NO:523

With regard to Group II the independent and distinct Inventions are as follows:

SEQ ID NO:4, SEQ ID NO:33, SEQ ID NO:44, SEQ ID NO:58, SEQ ID NO:64, SEQ ID NO:69, SEQ ID NO:71, SEQ ID NO:77, SEQ ID NO:82, SEQ ID NO:87, SEQ ID NO:90, SEQ ID NO:121, SEQ ID NO:129, SEQ ID NO:140, SEQ ID NO:154, SEQ ID NO:164, SEQ ID NO:170, SEQ ID NO:172, SEQ ID NO:174, SEQ ID NO:176, SEQ ID NO:184, SEQ ID NO:203, SEQ ID NO:287, SEQ ID NO:298, SEQ ID NO:309, SEQ ID NO:319, SEQ ID NO:325, SEQ ID NO:331, SEQ ID NO:341, SEQ ID NO:352, SEQ ID NO:366, SEQ ID NO:378, SEQ ID NO:385, SEQ ID NO:407, SEQ ID NO:409, SEQ ID NO:420, SEQ ID NO:429, SEQ ID NO:438, SEQ ID NO:440, SEQ ID NO:446, SEQ ID NO:457, SEQ ID NO:463, SEQ ID NO:482, SEQ ID NO:485, SEQ ID NO:494, SEQ ID NO:497, SEQ ID NO:499, SEQ ID NO:520, SEQ ID NO:522 and SEQ ID NO:524.

With regard to Group V the independent and distinct Inventions are as follows:

SEQ ID NO:63, SEQ ID NO:76, SEQ ID NO:81, SEQ ID NO:86, SEQ ID NO:89, SEQ ID NO:120, SEQ ID NO:128, SEQ ID NO:165, SEQ ID NO:183, SEQ ID NO:202, SEQ ID NO:218, SEQ ID NO:232, SEQ ID NO:274, SEQ ID NO:285, SEQ ID NO:286, SEQ ID NO:297, SEQ ID NO:317, SEQ ID NO:318, SEQ ID NO:320, SEQ ID NO:323, SEQ ID NO:324, SEQ ID NO:340, SEQ ID NO:377, SEQ ID NO:384, SEQ ID NO:406, SEQ ID

NO:408, SEQ ID NO:439 SEQ ID NO:445, SEQ ID NO:456, SEQ ID NO:481, SEQ ID NO:484, SEQ ID NO:493, SEQ ID NO:496, and SEQ ID NO:498.

With regard to Group VII the independent and distinct Inventions are as follows:
SEQ ID NO:165, SEQ ID NO:202, SEQ ID NO:210, SEQ ID NO:218, SEQ ID NO:227, SEQ ID NO:232, SEQ ID NO:248, SEQ ID NO:274, SEQ ID NO:285, SEQ ID NO:286, SEQ ID NO:297, SEQ ID NO:307, SEQ ID NO:308, SEQ ID NO:317, SEQ ID NO:318, SEQ ID NO:320, SEQ ID NO:323, SEQ ID NO:324, SEQ ID:329, and SEQ ID:330.

Inventions I and II are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case method of identifying compounds that modulates angiogenesis by interacting with nucleic acid sequences have different modes of operation, functions and effects as compared to the identification of compounds that interacts with a protein. For example a compound (i.e. antibody) that interacts with a protein involved in angiogenesis may not interact with the nucleic acid sequences (as claimed). Similarly an antisense molecule may not interact with the polypeptide sequences as claimed. Thus these inventions are distinct and are of separate uses.

Inventions I, III and inventions II, IV are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case method of screening compound in-vitro is distinct form the method of modulating angiogenesis in a subject. For example the method of screening compound identify a compound that interacts with a nucleic acid sequence or a polypeptide (as claimed) which requires DNA hybridization or antigen-antibody binding assay, where as modulation angiogenesis in vivo requires evaluation of blood vessels formation in a subject. Thus considering different modes of operation, different functions, or different effects these inventions are distinct and are of separate uses.

Inventions III, IV, V and VI are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case these methods requires the use of products which are structurally and functionally distinct from each other and have different modes of operation, different functions, or different effects. For example an antisense molecule is distinct from an antibody molecule, which are further distinct from a polypeptide or a nucleic acid sequences encoding the polypeptide. In addition the use of polypeptides is distinct form the nucleic acid encoding them, since polypeptides are biologically active compounds, whereas the nucleic acid sequences requires the use of an expression vector and host cells to express the encoded product. Thus these inventions are distinct and are of separate uses.

Inventions V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case besides the protein therapy the polypeptide of group VIII could also be used to make antibodies. Thus these inventions are distinct and are of separate uses.

Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In instant case besides using in a method for gene therapy the nucleic acid sequences of group VII could also be used to make recombinant proteins or genetic probes. Thus these inventions are distinct and are of separate uses.

Inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case polypeptide can also be isolated from cells endogenously expressing the polypeptide, rather than by recombinant means. Thus, these inventions are mutually exclusive and are of separate use.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

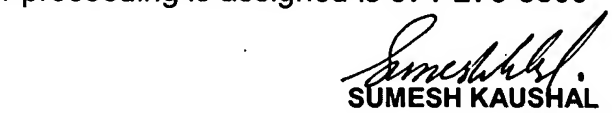
The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be

fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **571-272-0547.** For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**



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